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09/856,319		Hidetoshi Uemura	UEMURA 5	6685

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,319	UEMURA ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-33 and 35-43* is/are pending in the application.

4a) Of the above claim(s) *11-19,27-31,35-37,40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-26,32,33,38,39,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9,15* .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is the First Office Action on the Merits of the application filed May 21, 2001 as the U.S. National Stage of PCT/JP99/06473, filed November 11, 1999, which claims benefit of Japanese application 347806/1998 filed November 20, 1998. Preliminary amendments mailed August 15, 2001 (Paper Nos. 4 and 5), October 22, 2001 (Paper No. 7) and July 31, 2001 (Paper No. 10) have been entered in the case. This Office Action is a response to the "Reply to Restriction Requirement" filed October 30, 2002 (Paper No. 17). Claims 1-10 and 34 were cancelled, claims 35-43 were added and claims 11-15, 20, 22-27, 32 and 33 were amended in Paper No. 10. Claims 11-33 and 35-43 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group III (claims 20-26, 32, 33, 38, 39, 42 and 43) in Paper No. 17 (see additionally the attached Interview Summary) is acknowledged. The traversal is on several grounds.

First, Applicant asserts that the arguments presented in support of the restriction requirement are based on standard U.S. restriction practice rather than PCT rules. However, Applicant does not point out any specific flaws in the restriction requirement. To support the assertion that the restriction requirement has been improperly applied using U.S. restriction practice, Applicant points out that the IPER evidences no criticism on the bases of lack of unity-of-invention. In that regard, Applicant is reminded that 37 CFR §1.499 provides that the examiner may require the applicant to elect the invention to which the claims shall be restricted "at any time before the final action *at the discretion of the examiner.*"

Next, Applicant alleges that the claims of the elected Group III share a common special technical feature with claim 35 (Group II) because the claims "[depend] from and incorporate the subject matter of claim 35" (the paragraph bridging pages 2 and 3). This is not persuasive, however, because claim 35 is directed to an enzyme while the claims of Group III are directed to antibodies. Group III incorporates the subject matter of Claim 35 only to the extent that the claim limits the range of proteins to which the antibody can bind. Neither the structural nor the functional limitations of the enzyme of claim 35 are incorporated into the claims of Group II, as a protein having the structure and function of the enzyme to which claim 35 is directed would not function as an antibody. Therefore, the proteins embraced by Groups I and II are both structurally and functionally distinct and thus do not share a special technical feature. Furthermore, as pointed out in the original restriction requirement (Paper No. 16), "*[a]s the product claims do not represent a contribution over the prior art*, the claims lack a special technical feature that is the same as or that corresponds to a special technical feature of the other claimed inventions" (paragraph bridging pages 2 and 3).

Finally, Applicant argues that the restriction requirement would be improper even if U.S. restriction practice were in effect because examination of all of the claims in a single application would not constitute a serious burden. This argument is not found to be persuasive because, as pointed out by Applicant, restriction in the instant case is governed by PCT Rules 13.1 and 13.2, not U.S. restriction practice. Furthermore, even if U.S. rules were in effect, the inventions identified in the restriction requirement as Groups I-V could not be searched coextensively. For example, the databases that the PTO searches for protein and nucleic acid sequences are separate and cannot be searched coextensively. Furthermore, a search for the nucleic acid of Group I or

the polypeptide of Group II would not necessarily turn up the transgenic animal of group IV or inhibitor of serine protease activity of Group V. Because the inventions could not be searched coextensively, examination of all of the identified Groups in a single application would clearly constitute a serious burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-19, 27-31, 35-37, 40 and 41are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings are objected to for the reasons indicated on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

The disclosure is objected to because of the following informalities: The title is objected to for use of the word "novel", which is redundant with a patent. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims encompass antibodies that could be found in nature absent the hand of man. Amending the claims such that the hand of man is evident (e.g. directing them to an isolated antibody) would obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

In the instant case, the claims are directed to an antibody that reacts with a protein the limitations of which are set forth in claim 35, and compositions comprising and methods of using said antibody. The limitations of claim 35 are so broad, however, that the claim reads on a protein having any amino acid sequence. For example, in its most narrow embodiment, the protein of claim 35 is limited to a sequence composed of 231 amino acids that are "represented by" the 1st to 231st amino acids of SEQ ID NO:2 or 4. The polypeptide sequence as claimed is not limited to any particular arrangement of amino acids and is not limited to a protein having any function. The claim is more broadly directed to a polypeptide having an amino acid sequence derived from the above 231 amino acid protein by deletion, substitution or addition of one to several amino acids. Thus, the claims encompass antibodies, compositions comprising antibodies and methods of using antibodies that react with any polypeptide sequence that is longer or shorter or different from the 231 amino acid sequence composed of 231 amino acids that are "represented by" the 1st to 231st amino acids of SEQ ID NO:2 or 4. Although the derivatives of the polypeptide sequence are limited to polypeptides having the same "property" as the 231 amino acid protein, because the claim does not set forth any properties for the 231 amino acid protein, other than that it is a protein, the derivatives are again not limited to a protein having any function at all. In its broadest embodiment, the protein of claim 35, as set forth in part (i), is directed to a "modified derivative or fragment of" any of the proteins or modified proteins set forth in parts (a)-(h) of the claim. Thus, given their broadest reasonable interpretation, the claims of the instant application encompass an antibody, a composition comprising an antibody and a method of using an antibody that reacts with any amino acid sequence.

An adequate written description of an antibody requires more than a mere statement that it is part of the invention and a statement that it binds to some unspecified amino acid sequence; what is required is a description of the antibody itself or a specific antigen to which the antibody binds. It is not sufficient to define an antibody solely by a general biological property, i.e. it binds to protein, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any antibody with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all antibodies that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific antibodies, which bind to defined antigens and provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of all antibodies that bind to any polypeptide sequence. Therefore, only the described antibodies that bind to the sequences set forth as SEQ ID NO:2 and 4 meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 20-26, 32, 33, 38, 39, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that reacts with a protein comprising the sequence set forth in SEQ ID NO:2 and 4 and methods of using the antibody to detect pancreatitis, does not reasonably provide enablement for an antibody that binds to any and all polypeptides or methods of using an antibody that binds to a protein comprising SEQ ID NO:2 or 4 to detect or diagnose any condition other than pancreatitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and breadth of the claims: As described herein above, the claims are directed to an antibody, and compositions comprising and methods of using said antibody, that binds a protein having an amino acid sequence of unlimited size and composition, and unspecified function. Therefore the claims encompass products and methods of using an infinite number of antibodies most of which would bind proteins that have no known function. The

claims also encompass an antibody that binds to a protein comprising the sequence set forth as SEQ ID NO:2 and 4 and methods of using said antibody, or any antibody that binds to any protein, do detect pancreatitis (claim 32), all diagnostic markers (claim 42) and cancer (claim 43; please note that, as described below under 35 U.S.C. § 112, second paragraph, rejections, it has been assumed that Applicant intends claim 43 to depend from claim 42).

State of the prior art: The relevant art, which is well established and highly developed, does not provide a means to use any antibody regardless of the function of the antigen to which the antibody binds. Furthermore, the prior art is silent with regard to any correlation between expression of proteins comprising the sequence set forth as SEQ ID NO:2 or 4 and any disease state other than pancreatitis. Therefore, the skilled artisan must rely on the specification to teach how to use the claimed invention commensurate with its full scope.

Amount of direction provided by the inventor and existence of working examples: The teachings of the instant application are limited to antibodies that bind to proteins having the sequence set forth as SEQ ID NO:2 and 4, and a demonstration that said antibodies that bind to proteins having the sequence set forth as SEQ ID NO:2 and 4 can be used to detect pancreatitis in a rat model of pancreatitis (Example 6). Beyond that, the specification provides only general concepts that would enable the skilled artisan to make any polypeptide and raise an antibody against said polypeptide; although given the enormous scope of the claimed products the skilled artisan would not be able to make all of the claimed antibodies without having to engage in undue experimentation. On page 7, first full paragraph, the specification also teaches that some proteases contribute to the process of cancer metastasis by digesting the extracellular matrix surrounding the cancer cells. However, neither the specification nor the prior art teaches that the

presence or absence of the proteins disclosed in the instant application is in any way associated with any known cancer, let alone all cancers to which the claims are directed.

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is very high, given the enormous breadth of the claims and the limited of guidance in the specification and prior art, the skilled artisan would not be able to make or use the invention commensurate with the full scope of the claims without engaging in undue experimentation. To practice the full scope of the claimed invention the skilled artisan would first have to synthesize an infinite number of proteins differing in size and amino acid composition. Next, the skilled artisan would have to raise antibodies against the infinite number of synthesized proteins. Then, the skilled artisan would have to make an infinite number of monoclonal antibodies according to the method of claim 22, and identify antibodies from within the infinite pool that could be used according to the methods of claims 23-25, 32, 38, 39, 42 and 43.

With regard to claim 42, the skilled artisan would have to engage in undue experimentation to practice the claimed method over any scope other than the detection of pancreatitis because neither the specification nor the prior art suggests any correlation between the presence or absence of the proteins detected by the enabled and adequately described antibodies (i.e. antibodies that react with proteins comprising SEQ ID NO:2 or 4) and any condition other than pancreatitis. Therefore, the skilled artisan would have to resort to blind trial and error experimentation to find any disease state other than pancreatitis that could be diagnosed using the enabled antibody. The amount of experimentation required would certainly be undue. For these same reasons, claim 43 is not enabled over any scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are indefinite as the depend from claim 35, which is directed, in part (i), to a "modified derivative" of a protein. It is unclear whether the protein is limited to proteins produced by further modification of derivatized proteins only or if modification is the process by which the derivative protein is made. Claims 24, 25, 38 and 39 are also indefinite in their recitation of "modified derivative".

Claims 20-26, 32, 33, 38, 39, 42 and 43 are further indefinite as the depend from claim 35, which in parts (b), (d) (it is assumed that the part following (c) has been mistakenly labeled (b) instead of (d)), (f) and (h) is directed to a protein having "the same property" as the protein of parts (a), (c), (e) and (g), respectively. There is no antecedent basis for the term "property" in the claim and no properties are set forth other than amino acid composition and that the molecules are proteins.

Claims 20-23 are indefinite in the recitation of "a fragment thereof" in line 2 of claim 20, line 3 of claim 22, and line 4 or claim 23. it is unclear whether the fragment referred to is a fragment of the antibody or a fragment of the protein to which the antibody binds. Claim 21 is indefinite insofar as it depends from claim 20.

Claim 22 is indefinite in its recitation of "selecting the animal whose antibody titer is recognized" in lines 4-5. It is unclear what the animal's antibody titer is recognized by. It would seem that Applicant intends that the method comprises selecting an animal whose antibody titer recognizes the protein of claim 35, and amending the claim accordingly would obviate this rejection.

Claims 23-26, 38 and 39 are indefinite in being directed to a method of determining a protein or hBSSP5 in a specimen. If Applicant means that the protein is measured, it is unclear what aspect of the protein is determined. Alternatively, "determine" can also mean to fix the boundaries of an object, in which case it is unclear how the boundaries are to be fixed using the claimed method.

Claim 33 is indefinite in its being directed to a "pharmaceutical composition" to be used as a diagnostic. The Merriam-Webster online dictionary defines pharmaceutical as "a medicinal drug". It is unclear whether the preamble of the claim indicates that the composition is limited to only those compositions that can be used *in vivo*. In the interest of compact prosecution, the claim has been examined according to its broadest reasonable interpretation to encompass any composition that could be used in a diagnostic assay regardless of whether that composition could be used as a pharmaceutical.

Claims 23, 42 and 43 provide for the use of an antibody, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23, 42 and 43 are additionally is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 24 is also indefinite in its recitation of "a labeled antibody" in the fifth line. It is not clear what Applicant intends for this antibody to do, as there is no indication that the antibody binds to any of the other proteins set forth in the claim.

Claim 43 is indefinite in depending from claim 44. There is no claim 44 in the case. In the interest of compact prosecution, claim 44 has been examined with the assumption that the claim should depend from claim 42.

Claims 20-26, 32, 33, 38, 39, 42 and 43 are additionally rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are those recited in the nonelected base claim, claim 35.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note: The following rejection applies to the extent that the prior art discloses the same compositions and/or method embraced by the instant invention. The prior art rejection is not to be construed as an indication that the claimed or anticipated products and methods are *enabled* for the wide breadth of subject matter potentially embraced by the claims. The compositions

and/or methods disclosed in the prior art are essentially enabled to the same extent as the instant specification, since there is no significant difference in the level of guidance presented in either case.

Claims 20, 21, 23, 24, 26 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Carrere *et al.* (1986) *Biochim. Biophys. Acta* 883:46-53.

Carrere *et al.* teaches an antibody against human chymotrypsinogen A, which is encompassed by claims 20 and 21 as they are directed to an antibody against any protein (see 35 U.S.C. § 112, first paragraph, rejection herein above). In the paragraph bridging columns 1 and 2 on page 48 Carrere *et al.* teaches a method for determining a protein having the characteristics of protein (a) or (b) of claim 35, or modified derivative or fragment thereof, comprising detecting said protein with an antibody according to the methods of claims 23 and 24. The method of Carrere further comprises a specimen that is a body fluid according to claims 26 and 38 (see especially Table I).

The antibody and method taught by Carrere *et al.* are the same as those taught in the instant application; therefore the limitations of the claims are met by Carrere *et al.*

Claims 20, 21, 23, 25, 26 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Geokas *et al.* (1979) *J. Biol. Chem.* 254:2775-2781.

Geokas *et al.* teaches an antibody against human chymotrypsin II, which is encompassed by claims 20 and 21 as they are directed to an antibody against any protein. In the first paragraph on page 2776 and the section entitled "Radioimmunoassay for Human Pancreatic Chymotrypsin

II" bridging pages 2776 and 2777, Geokas *et al.* teaches a method for determining a protein having the characteristics of protein (a) or (b) of claim 35, or modified derivative or fragment thereof, comprising detecting said protein with an antibody according to the methods of claims 23 and 25. The method of Geokas further comprises a specimen that is a body fluid according to claims 26 and 39 (see especially Figure 2 and the caption thereto).

The antibody and method taught by Geokas *et al.* are the same as those taught in the instant application; therefore the limitations of the claims are met by Geokas *et al.*

Claims 20-23, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu *et al.* (1984; U.S. Patent No. 4,446,122).

Chu *et al.* teaches an antibody against human prostate specific antigen, which is encompassed by claims 20 and 21 as they are directed to an antibody against any protein. Chu *et al.* further teaches: a process for producing a monoclonal antibody against a protein having the characteristics of claim 35 (see especially Examples 26-29) according to claim 22; a method for determining the protein, which is based on immunological binding of an antibody against the protein according to claim 23; and a method for detecting a diagnostic marker for diseases wherein the marker is used for diagnosis of cancer according to claims 42 and 43 (see especially Example 23).

The antibody and method taught by Chu *et al.* are the same as those taught in the instant application; therefore the limitations of the claims are met by Chu *et al.*

Claims 20, 21, 23, 25, 26, 32, 33, 39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwaki *et al.* (1983) *Res. Commun. Chem. Pathol. Pharmacol.* 40:489-496.

Iwaki *et al.* teaches an antibody against human chymotrypsin II, which is encompassed by claims 20 and 21 as they are directed to an antibody against any protein. In item (5) on page 490 and references cited therein, Iwaki *et al.* teaches a method for determining a protein having the characteristics of protein (a) or (b) of claim 35, or modified derivative or fragment thereof, comprising detecting said protein with an antibody according to the methods of claims 23 and 25. The method of Iwaki *et al.* further comprises a specimen that is a body fluid according to claims 26 and 39 (see especially item (7) on page 490 and Figure 2 and the caption thereto). Iwaki *et al.* further teaches that the method described therein can be used for detecting a diagnostic marker for disease according to claim 42, wherein the disease is pancreatitis and the concentration of the protein is measured in blood according to claim 32 (see especially Figure 3 and the caption thereto). Thus, the antibody composition taught by Iwaki *et al.* is a composition for detecting pancreatitis according to claim 33.

The antibody, composition and method taught by Iwaki *et al.* are the same as those taught in the instant application; therefore the limitations of the claims are met by Iwaki *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesi *et al.* (1984) *Digestion* 30:114-115 in view of Carrere *et al.* (*supra).*

Lesi *et al.* teaches a method for detecting a diagnostic marker for disease in pancreas (i.e. pancreatitis), which comprises the protein according to claim 35 (i.e. Chymotrypsin). The method of Lesi *et al.* does not comprise using an antibody.

As described herein above, Carrere *et al.* teach an antibody against human chymotrypsinogen A and a method for determining chymotrypsinogen A in a specimen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Lesi *et al.* such that the diagnostic marker is detected using

the antibody and detection procedure of Carrere *et al.* according to the teachings set forth in the instant application and claimed in claim 42. Furthermore, the teachings of Lesi *et al.* demonstrate that the antibody of Carrere *et al.* can be used to diagnose pancreatitis; thus, the composition for detecting pancreatitis comprising the antibody according to claim 20, which is claimed in claim 33, would also be obvious to the ordinary skilled artisan at the time the instant application was filed.

Carrere *et al.* provides the motivation to combine these teachings, stating that "[e]nzyme levels in biological fluids are usually measured in terms of catalytic activity by sensitive and specific substrates. However, besides the fact that many factors may influence the measurement of catalytic activity, sensitive substrates may not be rigorously specific...The techniques of radio- or enzymoimmunoassay...may overcome this difficulty" (paragraph bridging columns 1 and 2 on page 46). Thus, Carrere points out the advantages of using immunoassays over the enzymatic assay taught by Lesi *et al.*

Absent any evidence to the contrary, one would have a reasonable expectation of success in combining the teachings of Lesi *et al.* and Carrere *et al.* because the antibody of Carrere *et al.* is raised against the same protein measured in the diagnostic method of Lesi *et al.*

Therefore, the inventions set forth in claims 33 and 42 would be *prima fascia* obvious to the ordinary skilled artisan at the time the instant application was filed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
January 4, 2003

JAMES KETTER
PRIMARY EXAMINER